K955270

AUG 8 1996

X. Summary of Safety and Effectiveness

Classification Name: Tape and Bandage, Adhesive
21 C.F.R. § 880.5240 (1994).

Common/Usual Name: Cutaneous Compression Device for General Hospital Use.

Proprietary Name: At present, no proprietary name has been chosen for this device.

Establishment Registration: Mr. Robert R. Stevens has not yet engaged in activities requiring establishment registration. Upon engaging in such activities, an establishment registration will be filed in accordance with the requirements set forth at 21 C.F.R. § 807.20 (1994).

Classification: Under Section 513 of the Federal Food, Drug, and Cosmetic Act, this device is classified into Class I.

Performance Standards: As of the date of this Premarket Notification submission, no Performance Standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act. As such, no actions have been taken to comply with Section 514 Performance Standards.

Labeling/Promotional Materials: Proposed labeling is included in this submission.

Substantial Equivalence: This device is substantially equivalent to the following legally-marketed device ("Predicate Device") in terms of safety, effectiveness, and intended use:

Product: Cutaneous Compression Device for Hemodialysis
Manufacturer: Mr. Robert R. Stevens
510(k) Number: K951973
Substantial Equivalence Date: Class I exempt.